

REMARKS

Status of the claims:

With the above amendments, claims 1, 14, 20, and 21 have been canceled and claims 2, 3, 13, and 17 have been amended. Claim 40 has been added. Thus, claims 2-13, 17-19, and 22-40 are pending and ready for further action on the merits. No new matter has been added by way of the above amendments. Support for the amendments to claims 2 and 3 can be found at page 8, 3rd paragraph. Claims 13 and 17 have been amended to change their dependency. Claim 40 has support in originally filed claim 16 and by canceled claim 1. Reconsideration is respectfully requested in light of the following remarks.

Claim Inquiry

Applicants note that claim 17 has not been rejected in any rejections but the Examiner has indicated in the Office Action Summary that claim 17 is rejected. Accordingly, Applicants inquire about the status of claim 17.

Rejections under 35 USC §102

Claim 1 has been rejected under 35 USC §102(b) as being anticipated by Hillebrand '500 (US Patent No. 5,296,500).

Claims 1-4, 6-7, 9, 13, 14, 18-25, 28-31, 34, and 38-39 have been rejected under 35 USC §102(b) as being anticipated by Neigut '461 (US Patent No. 5,378,461).

These rejections are traversed for the following reasons.

Regarding the rejection over Hillebrand '500, claim 1 has been canceled so the rejection is moot. Withdrawal of the rejection is warranted and respectfully requested.

Regarding the rejection over Neigut '461, the rejection is traversed. First, please note that claim 1 has been canceled so the rejection is moot with respect to claim 1.

Neigut '461 describes a balm for the topical treatment of skin damage comprising a mixture of a carrier, vitamins A, E and D and coenzyme Q₁₀ (please see claim 1 in Neigut '461). Example 5 of Neigut '461 discloses a composition comprising vitamins A, D and E, coenzyme CoQ₁₀, L-cysteine, L-methionine, zinc oxide and corn starch (see the table in Example 5). L-cysteine and L-methionine are sulfur based amino acids. The major inhibiting problem of using this preparation is the slightly disagreeable odor of sulfur compounds, which tend to intensify with body heat (see column 9, lines 1 and 2 and 57-59 in Neigut '461). Corn starch has been used as an effective binder to all ingredients. It does not impede skin penetration and gives a smooth velvety feel to the skin (see column 9, lines 14-16 in Neigut '461). The mixture of Example 5 is blended with corn starch in an

amount to achieve a desired viscosity (see column 9, lines 38 and 39 in Neigut '461).

However, it should be emphasized that corn starch is not a secondary plant substance as claimed in claims 2 and 3 of the invention. In column 9, lines 14 and 15, Neigut '461 discloses that corn starch has been used as an effective binder to all ingredients. Since Neigut '461 does not disclose a preparation comprising at least one secondary plant substance as claimed in claims 2 and 3 of the present invention, Neigut '461 cannot anticipate the instant invention because Neigut '461 fails to disclose the elements of the instantly claimed invention. Withdrawal of the rejection is warranted and respectfully requested.

Rejections under 35 USC §103

Claims 1, 2, 9-12, 14, 18-20, and 35-37 have been rejected under 35 USC §103(a) as being unpatentable over EP '812 (EP 0 281 812) in view of Gruber '043 (US Patent No. 4,593,043).

Claims 1, 2, 9-11, 14 and 18-20 have been rejected under 35 USC §103(a) as being unpatentable over Hillebrand '500 in view of Gruber '043.

Claims 8 and 32-33 have been rejected under 35 USC §103(a) as being unpatentable over Neigut '461 in view of Gruber '043.

Claims 5 and 26-27 have been rejected under 35 USC §103(a)

as being unpatentable over Neigut '461 in view of Ribier '833.

These rejections are traversed for the following reasons.

Present Invention

The present invention as claimed in claim 2 relates to a preparation for topical application comprising the following components:

- (a) at least one salt selected from alkali metal salts, alkaline earth metal salts and other minerals,
- (b) at least one amino acid,
- (c) zinc oxide and/or an inorganic peroxide, and
- (d) at least one secondary plant substance selected from the group consisting of carotinoids, phytosterols, saponins, polyphenols, flavonoids, terpenes, phytoestrogens, sulfides, phytin acid, dietary fibers and combinations thereof.

Disclosure of Hillebrand '500

Hillebrand '500 describes a method for regulating wrinkles or treating atrophy in mammalian skin comprising treating the skin with an effective amount of a composition comprising (a) N-acetyl-L-cysteine or a pharmaceutically-acceptable salt thereof, and (b) a pharmaceutically-acceptable carrier. The composition can additionally comprise a zinc salt (please see claims 1, 7

and 8). Example IV of Hillebrand '500 describes a sunscreen composition comprising sodium hydroxide, N-acetyl-L-cysteine and zinc oxide.

Hillebrand '500 fails to disclose the use of secondary plant substances.

Disclosure of Neigut '461

Neigut '461 describes a balm for the topical treatment of skin damage comprising a mixture of a carrier, vitamins A, E and D and coenzyme Q₁₀. (please see claim 1 in Neigut '461). Example 5 of Neigut '461 discloses a composition comprising vitamins A, D and E, coenzyme CoQ₁₀, L-cysteine, L-methionine, zinc oxide and corn starch (see the table in Example 5). L-cysteine and L-methionine are sulfur based amino acids. The major inhibiting problem of using this preparation is the slightly disagreeable odor of sulfur compounds, which tend to intensify with body heat (see column 9, lines 1 and 2 and 57-59 in Neigut '461). Corn starch has been used as an effective binder to all ingredients. It does not impede skin penetration and gives a smooth velvety feel to the skin (see column 9, lines 14-16 in Neigut '461). The mixture of Example 5 is blended with corn starch in an amount to achieve a desired viscosity (see column 9, lines 38 and 39 in Neigut '461).

Neigut '461 fails to disclose secondary plant substances.

Disclosure of EP '812

EP '812 discloses a composition for treatment of acne comprising a keratolytic agent, an astringent and an anti-inflammatory agent. The keratolytic or comedolytic agent is used to disintegrate the keratin plug and to aid in peeling the skin down to the follicle so that the follicle is opened to the skin's exterior. The astringent is used to assist in the complete emptying of the follicle by causing contraction of the lining cells of the follicle. A mild anti-inflammatory agent is also employed to suppress the body's damaging inflammatory reaction that occurs (see column 3, line 54 to column 4, line 6).

EP '812 does not teach any secondary plant substance. Furthermore, EP '812 does not disclose a salt selected from alkali metal salts, alkali earth metal salts and other minerals. Particularly, EP '812 neither discloses nor suggests the specific combination of components (a) to (d) or (a) to (e) as claimed in claims 2 or 3.

Disclosure of Gruber '046

Gruber '046 describes a process for reducing the skin irritation resulting from contact of the skin with benzoyl peroxide wherein aloe vera gel and benzoyl peroxide are admixed together prior to applying to the skin of a patient (see claim 1

in Gruber '046). Gruber '046 discloses to a person of ordinary skill in the art that aloe vera blended with benzoyl peroxide even at 20% concentration will reduce the skin irritations caused by the peroxide compound and enable the dermatologist to employ much higher potent concentrations with superior clinical results and no more irritation (see the paragraph bridging columns 1 and 2 in Gruber '046). The complete qualitative and quantitative chemistry of aloe vera gel has not been clearly defined and it is not a single chemical entity (see column 5, lines 12-14).

Gruber '046 fails to disclose the use of alkali metal salts, amino acids, zinc oxide, inorganic peroxide and particularly secondary plant substances.

Disclosure of Ribier '833

Ribier '833 describes a protective, nourishing and/or firming composition for the simultaneous treatment of the layers of the stratum corneum and deep layers of the skin, comprising a dispersion mixture of (a) a first dispersion of liquid vesicles, which are capable of penetrating into the deep layers of the skin and which contain at least one active agent selected from protective, nutritive and firming agents, and (b) a second dispersion of liquid vesicles. The dispersion of liquid vesicles are capable of penetrating into the layers of the

stratum corneum. The dispersion mixture comprises at least one active agent selected from protective and nutritive agents (see claim 1). Zinc oxide is mentioned as an example of a pigment in column 6, lines 65 et seq. Ribier '833 discloses at column 6, second paragraph that plant extracts may be used, such as cytoplasmic juices from plants and especially from seaweed or from plant cells cultured in a fermenter.

Ribier '833 does not disclose a composition having a combination of components as claimed in claim 2 or claim 3. Ribier '833 provides no disclosure regarding the quantitative or qualitative components in the cytoplasmic juices from said plant extracts. In particular, there is no disclosure in Ribier '833 that points to secondary plant substances as claimed in the present invention.

Removal of the Rejections over EP '812 in view of Gruber '043, Hillebrand '500 in view of Gruber '043, Neigut '461 in view of Gruber '043, and Neigut '461 in view of Ribier '833

Claim 1 has been canceled. Thus, the rejections with respect to this claim are moot.

Regarding the rejections over EP '812 in view of Gruber '043, Hillebrand '500 in view of Gruber '043, and Neigut '461 in view of Gruber '043, these rejections are traversed. Amended independent claims 2 and 3 cannot be rendered obvious by EP '812 in view of Gruber '043, Neigut '461 in view of Gruber '043, or

Hillebrand '500 in view of Gruber '043 because none of the references disclose or suggest secondary plant substances. There is no disclosure of suggestion in Hillebrand '500 pointing to the use of secondary plant substances in cosmetics or preparations for topical application at all. Further, Neigut '461, EP '812, and Gruber '043 do not mention or suggest any secondary plant substances.

Accordingly, Applicants assert that the Examiner has failed to make out a *prima facie* case of obviousness with regard to the 35 USC §103(a) rejections over EP '812 in view of Gruber '043 and Hillebrand '500 in view of Gruber '043. Three criteria must be met to make out a *prima facie* case of obviousness.

- 1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.
- 2) There must be a reasonable expectation of success.
- 3) The prior art reference (or references when combined) must teach or suggest all the claim limitations.

See MPEP §2142 and *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). In particular, the Examiner has failed to meet the third element to make a *prima facie* obviousness rejection. As mentioned above, EP '812, Neigut '461, Gruber '043 and Hillebrand '500 all fail to disclose or suggest secondary plant substances. The

rejection is inapposite. Withdrawal of the rejection is warranted and respectfully requested.

EP '812, Gruber '043 and Hillebrand '500 do mention corn starch. However, it should be noted that starch is a reserve polysaccharide in plants such as corn. It is a carbohydrate polymer composed of about 25% amylose and 75% amylopectin. However, corn starch is not a secondary plant substance as claimed in claims 2 and 3 of the invention. In column 9, lines 14 and 15, Neigut '461 discloses that corn starch has been used as an effective binder to all ingredients. Since Neigut '461 does not disclose a preparation comprising at least one secondary plant substance as claimed in the present invention, the present invention is novel over Neigut '461.

Moreover, Neigut '461 discloses at column 9, lines 1 and 2 and 57-59 that certain sulfur based amino acids could be used, but a preparation comprising these amino acids has the major problem of sulfur compounds' disagreeable order, which tend to intensify with body heat. In other words, Neigut '461 teaches away from the use of sulfur based amino acids. Furthermore, Neigut '461 does not point to any other amino acids. However, as mentioned above, Neigut '461 is silent concerning secondary plant substances as claimed in claims 2 and 3. Particularly, there is nothing in Neigut '461 pointing to preparations comprising the specific combination of components according to

claims 2 and 3. Therefore, the subject-matter of the present invention cannot be rendered obvious by the disclosure of Neigut '461, whether used alone or in combination with Gruber '043.

EP '812 also does not teach any secondary plant substance. Furthermore, EP '812 does not disclose a salt selected from alkali metal salts, alkali earth metal salts and other minerals. Particularly, EP '812 neither discloses nor suggests the specific combination of components (a) to (d) or (a) to (e) as claimed in claims 2 and 3, respectively.

It should be further noted that EP '812 discloses the discovery that a mild anti-inflammatory agent can be combined with a keratolytic agent which facilitates the opening and emptying of the contents of the engorged follicle onto the skin surface. That is, EP '812 discloses a preparation, which mainly acts at the surface of the skin. This is different from the preparations of the present invention, which mainly act on the deeper layers of the skin. There is no indication in EP '812 of any teaching that the combination of amino acids and zinc oxides and/or inorganic peroxides improves the microcirculation in the cells. Further, there is nothing in EP '812 pointing to secondary plant substances at all. Therefore, a person of ordinary skill in the art would disregard EP '812 when searching for a solution to the object of the instant invention.

Gruber '046 also fails to disclose the use of alkali metal salts, amino acids, zinc oxide, inorganic peroxide, and particularly, secondary plant substances. Benzoyl peroxide used in Gruber '046 is not an inorganic peroxide. Gruber '046 uses a gel of aloe vera and indicates that the chemistry of aloe vera gel has not been clearly defined. There is no indication in Gruber '046 that the gel used comprises any secondary plant substances. That is, there is nothing in Gruber '046 that suggests or provides any hint to a preparation comprising the specific combination of components as claimed in claims 2 and 3. Gruber '046 bases its teaching on how to reduce skin irritations caused by benzoyl peroxide. However, there is nothing in Gruber '046, which would render the instant invention obvious to a person of ordinary skill in the art.

The combination of Gruber '046 with EP '812 does not make obvious a preparation according to claims 2 and 3 to a person of ordinary skill in the art, either. Neither Gruber '046 nor EP '812 mentions or provides any indication to use secondary plant substances. Moreover, Gruber '046 and EP '812 do not use alkali metal salts, alkaline earth metal salts or other minerals in combination with zinc oxide or an inorganic peroxide. Accordingly, the subject-matter of claims 2 and 3 cannot be rendered obvious from a combination of Gruber '046 and EP '812.

As mentioned above, Hillebrand '500 is silent regarding secondary plant substances as claimed in the present invention. The Examiner acknowledges this on page 4, lines 5 and 6 of the Office Action.

As mentioned above, Gruber '046 describes an aloe vera gel, but indicates that the qualitative and quantitative chemistry of the aloe vera gel has not been clearly defined. Gruber '046 is silent concerning secondary plant substances. It should be noted that aloe vera also optionally could be used in preparations of the present invention. However, as can be seen from the last paragraph of page 6, it is used as a humectant. However, again, Gruber '046 does not disclose or suggest any secondary plant substances as claimed in the present invention. Furthermore, it should be noted that Hillebrand '500 describes a method for regulating wrinkles or atrophy in mammalian skin, whereas Gruber '046, in contrast, discloses a process for reducing skin irritations resulting from contact of the skin with benzoyl peroxide. Because the described methods clearly relate to different medical indications, Applicants assert that there is no motivation for a person of ordinary skill in the art to combine these references. That is, since the person of ordinary skill would not combine these references and none of these references suggest secondary plant substances, the present

invention cannot be rendered obvious by the combination of Hillebrand '500 and Gruber '046.

Neigut '461 describes a balm for topical treatment of skin damage. As mentioned above, Example 5 of Neigut '461 uses corn starch as an effective binder to all ingredients. The corn starch is used in an amount to achieve a desired viscosity (see particularly, column 9, lines 14-15 and lines 38-39 of Neigut '461). Furthermore, as mentioned above, Neigut '461 teaches against the use of sulfur based amino acids and does not mention other amino acids. Corn starch as mentioned above is a polysaccharide, but not a secondary plant substance. Because both Neigut '461 and Gruber '046 are silent regarding secondary plant substances, a combination of these documents does not render obvious a preparation according to claims 2 or 3 of the present invention. Furthermore, it should be noted that Gruber '046 discloses using aloe vera gel in order to reduce the skin irritation resulting from contact of the skin with benzoyl peroxide. Because Neigut '461 does not use benzoyl peroxide, there is no motivation for a person of ordinary skill in the art to combine this reference with that of Gruber '046.

Ribier '833 does not disclose a composition having a combination of components as claimed in claim 2 or claim 3. Ribier '833 provides no disclosure regarding the quantitative or qualitative components in the cytoplasmic juices from said plant

extracts. In particular, there is no disclosure in Ribier '833 that points to secondary plant substances as claimed in the present invention.

It should be emphasized that a plant extract does not necessarily contain secondary plant substances in an effective amount. For example, vegetable oils, which may be regarded as a plant extract, comprise unsaturated fatty acids but not secondary plant substances. It should be further noted that there is no teaching or suggestion in Ribier '833 that a combination of amino acids and zinc oxide or inorganic peroxide has any improving effects on the microcirculation of cells. Moreover, there is no disclosure or suggestion or any working examples in Ribier '833 that point to the specific combination of amino acid, zinc oxide and/or inorganic peroxide and secondary plant substances. That is, Ribier '833 neither discloses nor suggests the subject-matter of the present invention which.

Thus, contrary to the allegations of the Examiner, the subject-matter of the present invention cannot be rendered obvious by the combination of Ribier '833 and Neigut '461. As mentioned above, in Example 5 of Neigut '461, corn starch is used as an effective binder to all ingredients and to achieve a desired viscosity. However, corn starch is not a secondary plant substance. That is, there is no hint in Neigut '461 that

points to any secondary plant substances. There is also no indication in Neigut '461 that a combination of secondary plant substances with amino acids and zinc oxide and/or inorganic peroxide has any improving effects on cell microcirculation. As mentioned above, Ribier '833 is also silent with respect to secondary plant substances. Ribier '833 discloses to a person of ordinary skill in the art that different layers of the skin can be simultaneously treated by a composition comprising a first dispersion of liquid vesicles for the deep layers and a second dispersion of liquid vesicles for layers of the stratum corneum. The vesicles can have active agents as desired. However, there is no disclosure or suggestion in Ribier '833 with respect to specific combinations of active agents. That is, there is no motivation for a person of ordinary skill in the art to combine a specific active agent disclosed in Ribier '833 with specific components disclosed in Neigut '461. Because none of Neigut '461 and Ribier '833 disclose secondary plant substances as claimed in the present invention, a combination of these documents does not render obvious the subject-matter of the present invention.

For the above reasons, none of EP '812, Gruber '043, Hillebrand '500, Neigut '461 or Ribier '833 can render obvious the instant invention either used separately or combined. The rejections over these references are inapposite. Withdrawal of

the rejections is warranted and respectfully requested.

Furthermore, even if any of the references had disclosed a secondary plant substance, which Applicants do not concede, Applicants assert that the Examiner would be employing hindsight reconstruction to arrive at the instant invention. Only knowledge in advance of the presently claimed invention could lead one of skill in the art to the combination that is taught in the instant invention. However, to "imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art references or record convey or suggest that knowledge is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *W.L. Gore & Assoc. v. Garlock, Inc.* 220 USPQ 303, 311 (Fed. Cir., 1983).

It is recognized that in examining an application that a little hindsight reconstruction is necessary and allowed. However, Applicants assert that the Examiner is using more hindsight than is allowed. Removal of the rejections is warranted and respectfully requested.

With the above remarks and amendments, it is believed that the claims, as they now stand, define patentable subject matter such that a passage of the instant invention to allowance is warranted. A Notice to that effect is earnestly solicited.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of \$930.00 is attached hereto.

If any questions remain regarding the above matters, please contact Applicant's representative, T. Benjamin Schroeder (Reg. No. 50,990), in the Washington metropolitan area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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By  _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1, 14, 20 and 21 have been canceled.

The claims have been amended as follows:

2. (Amended) A preparation for [the] topical application comprising the following components:

- (a) at least one salt selected from alkali metal salts, alkaline earth metal salts and other minerals,
- (b) at least one amino acid,
- (c) zinc oxide and/or an inorganic peroxide, and
- (d) at least one secondary plant substance selected from the group consisting of carotinoids, phytosterols, saponins, polyphenols, flavonoids, terpenes, phytoestrogens, sulfides, phytin acid, dietary fibers and combinations thereof.

2. (Amended) Preparation comprising the following components:

- (a) at least one salt selected from alkali metal salts, alkaline earth metal salts and other minerals,
- (b) at least one amino acid,
- (c) zinc oxide and/or an inorganic peroxide,
- (d) at least one secondary plant substance selected from the group consisting of carotinoids, phytosterols, saponins, polyphenols, flavonoids, terpenes,

phytoestrogens, sulfides, phytin acid, dietary fibers
and combinations thereof, and

- (e) at least one polyunsaturated fatty acid of vegetable sources.

13. (Amended) [The] A method of administering a preparation as described in [according to] claim 3 where the preparation is administered topically.

17. (Amended) A method of administering a preparation as described in claim [4] 2, wherein said preparation is administered topically [applied].

Claim 40 has been added.